K120990

510(k) Summary

JUN 29 2012

Submitter:	Zimmer Trabecular Metal Technology, Inc. 10 Pomeroy Road Parsippany, New Jersey 07054
Contact Person:	Judith Rosen Senior Regulatory Affairs Specialist Telephone: (973) 576-0032 ext 28138 Fax: (973) 884-8792
Date:	March 30, 2012
Trade Name:	NexGen® LCCK Trabecular Metal™ Coupled Tibial Cones™
Common Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented and uncemented
Classification Name:	"Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis"; and "Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis"
Reference:	21 CFR § 888.3560, JWH and 21 CFR § 888.3565, MBH

DEVICE DESCRIPTION

The NexGen® LCCK Trabecular Metal™ Coupled Tibial Cones™ are manufactured of Trabecular Metal™, porous tantalum with titanium alloy screws and screw inserts. The proposed TM Coupled Tibial Cones intend to combine the function of TM Tibial Augments and TM Tibial Cone Augments. The TM Coupled Tibial Cone design uses the same cavitary filling geometries of the TM Tibial Cone Augment and the mating functions of the TM Tibial Augment to specifically address small to medium segmented, contained, cavitary bony defects of the proximal tibia found during revision surgery. The TM Coupled Tibial Cone design provides the use of mechanical attachment to the tibial baseplate to allow for modularity and intra-operative assembly. The design is intended to provide stability to the tibial baseplate construct after reconstruction of the proximal tibia when subjected to normal gait activities.

INDICATIONS FOR USE

The Trabecular Metal LCCK Coupled Tibial Cones are intended for use where severe degeneration, trauma, or other pathology of the knee joint indicates total knee arthroplasty. When used with the NexGen Complete Knee Solution – Legacy Constrained Condylar Knee System, the Trabecular Metal Coupled Tibial Cones are for cementless or cemented use.

DEVICE TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICES

The NexGen® LCCK Trabecular Metal™ Coupled Tibial Cones™ were shown to be substantially equivalent to the legally marketed predicate devices. These predicates include Zimmer's NexGen® Trabecular Metal™ Tibial Cone Augments (K102896, K031962, K053340), and Zimmer's NexGen® Complete Knee Solution - Trabecular Metal™ Augments (K024161, K040487).

The NexGen® LCCK Trabecular Metal™ Coupled Tibial Cones™ have the same material as the previously cleared predicate devices. The intended use and indications for use of the subject devices are the same as that of the predicate devices. This Traditional Premarket Notification 510(k) submission is to introduce a version of the cone augments to address a wider range of defects. This configuration incorporates the same technological characteristics and design features as the predicate devices.

There are no significant differences between the proposed NexGen® LCCK Trabecular Metal™ Coupled Tibial Cones™ and the predicates currently being marketed. Any differences in technological characteristics do not raise new issues of safety and efficacy.

PERFORMANCE DATA

A comparative Finite Element Analysis (FEA) study was performed to evaluate the strength of the proposed TM Coupled Tibial Cone designs across different normal gait activities (walking, stair ascent/decent and deep flexion). The results of testing and analysis conducted demonstrate that the proposed implant adequately meets the predetermined requirements established for its mechanical performance, supporting substantial equivalence to the predicate.

CONCLUSION

The NexGen® LCCK Trabecular Metal™ Coupled Tibial Cones™ are the same as the predicate device with respect to intended use/indications for use, technological characteristics and basic principles of operation. This product does not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer Trabecular Metal Technology
% Ms. Judith Rosen
Senior Regulatory Affairs Specialist
10 Pomeroy Road
Parsippany, New Jersey 07054

JUN 29 2012

Re: K120990
Trade/Device Name: NexGen® LCCK Trabecular Metal™ Couples Tibial
Regulation Number: CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: MBH, JWH
Dated: March 30, 2012
Received: April 02, 2012

Dear Ms. Rosen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120990

Device Name: **NexGen® Trabecular Metal™ LCCK Coupled Tibial Cones™**

Indications for Use:

The Trabecular Metal LCCK Coupled Tibial Cones are intended for use where severe degeneration, trauma, or other pathology of the knee joint indicates total knee arthroplasty. When used with the NexGen Complete Knee Solution – Legacy Constrained Condylar Knee System, the Trabecular Metal Coupled Tibial Cones are for cementless or cemented use.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120990